EXHIBIT F

18-01

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Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

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Date: FEB 22 2018

Debra M. Parrish
788 Washington Road
Pittsburgh, PA 15228-2021

NOTICE OF DECISION

Appellant: J. BLOOM
OMHA Appeal Number: 1-7164213198

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's health insurance claim number;
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod**.

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of

decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

C2C Innovative Solutions, Inc.
DME QIC Appeals–ALJ
P.O. Box 44006
Jacksonville, FL 32231-4006

Enclosures:

OMHA-152, Decision
OMHA-156, Exhibit List
DAB-101, Request for Review

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Seattle, Washington

Appeal of:	**J. BLOOM**	OMHA Appeal No.:	**1-7164213198**
Beneficiary:	**J. BLOOM**	Medicare:	**Part B**
HICN:	*****9397A**	Before:	**P. Arthur McAfee** Administrative Law Judge

DECISION

After carefully considering the evidence, a **FULLY FAVORABLE** decision is issued in the appeal of J. Bloom (Appellant/Beneficiary).

Procedural History

The Beneficiary received invasive (e.g. subcutaneous), disposable sensors for use with an interstitial continuous glucose monitoring system (CGM), (A9276), dates of service June 8, 2017 and July 14, 2017. The Medicare Administrative Contractor (MAC) denied Medicare coverage upon initial determination and again on redetermination review. On January 4, 2018, C2C Innovative Solutions, Inc., the Medicare Qualified Independent Contractor (QIC), upheld the prior denials of coverage upon reconsideration review. (Ex. 1 at 2-7).

On January 11, 2018, the Office of Medicare Hearings and Appeals (OMHA) received Appellant's timely Request for an Administrative Law Judge (ALJ) hearing. (Ex. 3 at 1-2).

Pursuant to proper notice, a telephonic hearing was held on February 12, 2018, from the OMHA Seattle Field Office. The Appellant testified at the hearing, and was represented by his attorney Bridget Noonan of Parrish Law Offices. (Hearing Testimony). Exhibits 1 through 4 were admitted into the record without objection. Post hearing, the Appellant submitted additional documents, including a recent U.S. District Court decision, a position paper, and a petition for approval of attorney fees. Those documents are incorporated into the record as Exhibit 5.

The Appellant requested an aggregation of this claim with several other claims pending at the QIC and/or heard by a different OMHA ALJ. (Hearing Testimony). The request for aggregation was made for the first time during oral arguments during the hearing. For reasons described in C.F.R. §405.1006, that request is denied. In order for an appellant to aggregate claims, the appellant must make the request in the same request for ALJ hearing, or in multiple requests for an ALJ hearing filed with the same request for aggregation. C.F.R. §405.1006(e)(2). The

undersigned notes that the remaining criteria for aggregating the requested claims are met: the claims involve the delivery of similar or related services, involving common issues of law and fact.

The Appellant also submitted a request for attorney's fees and expenses incurred in this appeal, in a document entitled Petition to Obtain Approval of a Fee for Representing a Claimant Before OMHA. (Exh. 5, p. 34). Subject to a review of the reasonableness of the requested fee, the undersigned accepts the Petition to Obtain Approval of a Fee, pursuant to C.F.R. §405.910(f). The undersigned notes that a request for representative fees is available for services rendered in connection with an appeal before the Secretary, and that services rendered below the OMHA level are not considered proceedings before the Secretary.

Issues

Whether the disposable sensors for use with an interstitial continuous glucose monitoring system (A9276), dates of service June 8, 2017 and July 14, 2017, that the Beneficiary received are covered in accordance with the applicable Medicare rules and regulations? If Medicare coverage is denied, a subsequent issue is who is financially liable under §1879 of the Act?

Findings of Fact

After careful consideration of the entire record (Exhibit List attached and incorporated herein), a preponderance of the evidence establishes the following facts:

The Beneficiary is a 72 year old retired dentist, grandfather, and avid skier. (Hearing Testimony). He is also a brittle Type I diabetic who is unable to detect sudden drops in his blood sugar levels. He has suffered from diabetes for over 40 years and has difficulty controlling his insulin swings, regardless of how much he controls his diet or lifestyle. To complicate this condition, the Beneficiary also has "hypoglycemic unawareness", which means that he does not experience a nervous system response such as palpitations, sweating, or anxiety prior to sudden drops in his blood glucose levels. (Exh. 2, pp. 1-10).

The Beneficiary was provided with a Medtronic-MiniMed ("MiniMed") continuous glucose monitor, which is a sensor system that is designed to continuously and automatically monitor interstitial glucose values in the subcutaneous tissue. The MiniMed CGM consists of three parts: a sensor, a transmitter, and a receiver. The disposable sensor is the component at issue in this appeal. As a whole, the MiniMed estimates blood glucose levels and alerts the user if the levels are too high or too low, and also tracks trends in glucose levels. The user is advised to confirm those levels with the traditional finger-stick method before making a decision about administering insulin. (Exh. 2, pp. 11-13).

In a letter to the Medicare Administrative Contractor that denied coverage for his MiniMed CGM, the Beneficiary related several life-threatening episodes due to sudden, unpredictable blood sugar fluctuation that resulted in hospitalization. In 1984, while on a ski trip in Lake Tahoe, his two children were unable to awaken him until emergency paramedics arrived. In 2005, his wife was unable to awaken him, and again in 2008 he failed to wake up on a transcontinental flight. The letter reminds the contractor that the Beneficiary has already

appealed the denial of this same CGM, winning favorable decisions before administrative law judges at OMHA, on nine separate occasions. (Exh. 1, p. 28).

In addition, the record contains a letter from Dr. Richard Pratley at the Vermont Regional Diabetes Center, in which Dr. Pratley explains that in spite of a 35-year Type I diabetes history, the Beneficiary's "scrupulous glycemic control over the years" has resulted in "virtually no significant microvascular complications." The letter states that the Beneficiary's use of the MiniMed "has markedly improved his management, quality of life and overall safety." (Exh. 2, p. 12). A letter from his endocrinologist describes frequent hypoglycemic episodes, but that "when he is wearing his sensor he gets reliable alarms and is able to react appropriately… I think it is essential that he continue on insulin pump therapy with continuous glucose monitoring." (Exh. 2, pp. 13-14).

The record contains a copy of the opinion and order of the United States District Court for the District of Vermont, ***** *v. Azar*, 5:16-cv-121 (Vt. Jan. 30, 2018). (Exh. 5). The Plaintiff in that case is the Beneficiary in this appeal, and the issue, in short, is whether or not the Beneficiary's MiniMed meets Medicare criteria for coverage. The opinion and order describe that court's determination that the MiniMed qualifies as DME; that the disposable sensors (the item at issue in this appeal) are supplies or accessories necessary for the effective use of the equipment; and that the MiniMed is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The Court instructed the Secretary to authorize coverage for the MiniMed at issue. *(***** *v. Azar*, 5:16-cv-121 at 24-25).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Act § 1869(b)(1)(A); 42 C.F.R. § 405.1014. In implementing the statutory directive, the Secretary delegated the authority to administer the nationwide hearings and appeals systems for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). ALJs in OMHA issue final decisions of the Secretary, excluding decisions reviewed by the Medicare Appeals Council *(Id.)*.

For requests filed in 2017, the minimum amount remaining in controversy required before an ALJ is $160.00 (following application of any co-insurance or deductible). *See* Act § 1869(b)(1)(E); 42 C.F.R. § 405.1006; 80 Fed. Reg. 57827 (Sept. 25, 2015).

To be considered timely, the request for hearing must be received by OMHA within 60 days after the Appellant receives the QIC's reconsideration decision. The Appellant is presumed to have received the QIC's reconsideration decision five days after the date noted on the first page

of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. §§ 405.1002 and 405.1014.

B. Scope of Review

The issues before the ALJ include all issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the appellant's favor. 42 C.F.R. § 405.1032(a). If evidence presented before a hearing causes an ALJ to question a favorable portion of a determination, the ALJ may notify the parties before the hearing and consider it an issue at the hearing (*Id.*).

C. Standard of Review

The ALJ conducts a *de novo* review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedure Act (APA). *De novo* review means the ALJ independently assesses evidence without regard to prior findings made on the claim and makes an independent assessment based upon applicable law and policy. The burden of proving each element of a Medicare claim lies with the appellant by preponderance of the evidence (i.e., is satisfied by submitting sufficient evidence in accordance with program requirements). *See* Act §§ 1814(a)(1), 1815(b), and 1833(e); *see also* 42 C.F.R. §§ 405.1018, 405.1028, 405.1030, and 424.5(a)(6).

II. Principles of Law

A. Statutes and Regulations

Section 1831 of the Act establishes the Supplemental Medical Insurance Program for the aged and disabled under Part B. Act § 1831. Section 1832 of the Act establishes the scope of benefits that are provided to beneficiaries under the Medicare Part B insurance program. Act § 1832; *see also* 42 C.F.R. §410.3. Under §1832(a)(2)(B) of the Act, an individual is entitled to have payment made on his/her behalf for medical and other health services furnished by a provider of services or by others under arrangement with them made by a provider of services. Act § 1832(a)(2)(B).

Section 1833(e) of the Act states that no payment can be made to the provider or another person unless such information, as may be necessary, has been furnished in support of the medical necessity of the claimed services in order to determine the amount due such provider or other individual. Act § 1833(e); *see also* 42 C.F.R. § 424.5(a)(6).

Section 1834 of the Act defines the rules for payment of covered items of durable medical equipment. Act § 1834.

Section 1861(s) of the Act defines "medical and other health services" to include physician services and services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills (or would have been so included but for the application of section 1847B). Act § 1861(s).

Section 1861(s)(6) of the Act defines the term "medical and other health services" to specifically include durable medical equipment. Act § 1861(s); *see also* 42 C.F.R. § 410.10(h).
Section 1862(a)(1)(A) of the Act provides that notwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Act § 1862(a)(1)(A).

42 C.F.R. § 410.38 covers the scope and conditions regarding durable medical equipment. 42 C.F.R. § 410.38.

42 C.F.R. § 414.202 defines durable medical equipment as equipment, furnished by a supplier or a home health agency that-

(1) Can withstand repeated use;
(2) Is primarily and customarily used to serve a medical purpose;
(3) Generally is not useful to an individual in the absence of an illness or injury; and
(4) Is appropriate for use in the home.

42 C.F.R. § 414.202.

B. Policy and Guidance

The Medicare program is administered through the Centers for Medicare and Medicaid Services (CMS), a component of the United States Department of Health and Human Services. Under the authority of Section 1842(a) of the Act, the Secretary of the Department of Health and Human Services is authorized to enter into contracts with private entities for the day-to-day operations of the program. Act § 1842(a). In order to further implement the Act, CMS issued National Coverage Determinations (NCDs). Pursuant to section 1869(f)(1)(A)(i) of the Act, an ALJ may not set aside or review a NCD. Act § 1869(f)(1)(A)(i). As such, the ALJ must follow the criteria for coverage set out by the NCD as it applies to the particular case. Relevant to the case at hand is NCD 40.2 for Home Blood Glucose Monitors.

Section 1871(a)(2) of the Act states that "[n]o rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation." Act § 1871(a)(2); *see also* 42 C.F.R. § 405.1060. In lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance describing the criteria for coverage of selected items and services in the form of manuals and local coverage determinations (LCDs), respectively.

Although ALJs are not bound by LCDs or CMS program guidance, such as program memoranda and manual instructions, an ALJ will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a). If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An

ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect. 42 C.F.R. § 405.1062(b). The authority to promulgate manuals and other policy issuances is found, in part, in Section 1842 of the Act.
The *National Coverage Determination* (NCD) for Home Blood Glucose Monitors, CMS Publication 100-3, Chapter 1, section 40.2, effective date June 19, 2006, states in relevant part:

> There are several different types of blood glucose monitors that use reflectance meters to determine blood glucose levels. Medicare coverage of these devices varies, with respect to both the type of device and the medical condition of the patient for whom the device is prescribed.
>
> [. . .]
>
> . . . coverage of home blood glucose monitors is limited to patients meeting the following conditions:
>
> 1. The patient has been diagnosed as having diabetes;
> 2. The patient's physician states that the patient is capable of being trained to use the particular device prescribed in an appropriate manner; . . .
> 3. The device is designed for home rather than clinical use.

NCD 100-3, Ch. 1, § 40.2.

Additionally, Noridian Local Coverage Determination (LCD) L33822, entitled *Glucose Monitors*, for services performed after January 12, 2017, provides, in relevant part, further guidance on glucose testing supplies:

> Coverage Indications, Limitations and/or Medical Necessity
>
> For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.
>
> The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.
>
> In addition to the "reasonable and necessary" criteria contained, there are other payment rules, which are discussed in the following documents that must also be met prior to Medicare reimbursement:
>
> - The LCD-related Standard Documentation Requirements Article . . .
> - The LCD-related Policy Article . . .
>
> [. . .]

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

HOME BLOOD GLUCOSE MONITORS (BGM)

To be eligible for coverage of home blood glucose monitors and related accessories and supplies, the beneficiary must meet both of the following basic criteria (1) – (2):

1. The beneficiary has diabetes (Reference ICD-10 Codes that Support Medical Necessity section for applicable diagnoses); and

2. The beneficiary's physician has concluded that the beneficiary (or the beneficiary's caregiver) has sufficient training using the particular device prescribed as evidenced by providing a prescription for the appropriate supplies and frequency of blood glucose testing.

For all glucose monitors and related accessories and supplies, if the basic coverage criteria (1)-(2) are not met, the item(s) will be denied as not reasonable and necessary.

[. . .]

CONTINUOUS GLUCOSE MONITORS (CGM)

CGM devices covered by Medicare under the DME benefit are defined in CMS Ruling 1682R as therapeutic CGMs. . . .

Therapeutic CGMs and related supplies are covered by Medicare when all of the following coverage criteria (1-6) are met:

1. The beneficiary has diabetes mellitus (Reference ICD-10 Codes that Support Medical Necessity section for applicable diagnoses); and,

2. The beneficiary has been using a BGM and performing frequent (four or more times a day) testing; and,

3. The beneficiary is insulin-treated with multiple (three or more) daily injections of insulin or a Medicare-covered continuous subcutaneous insulin infusion (CSII) pump; and,

4. The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results; and,

5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-4) above are met; and,

6. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan.

When a therapeutic CGM (code K0554) is covered, the related supply allowance (code K0553) is also covered.

If any of coverage criteria (1-6) are not met, the CGM and related supply allowance will be denied as not reasonable and necessary.

LCD L33822.

Also considered was Local Coverage Policy Article A52464 for Glucose Monitors, Policy Article V10 (effective January 12, 2017) states, in relevant part:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Home blood glucose monitors are covered under the Durable Medical Equipment benefit [Social Security Act §1861(s)(6)]. In order for a beneficiary's DME to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Continuous glucose monitoring (CGM) devices covered by Medicare under the DME benefit are defined in CMS Ruling 1682R as therapeutic CGM. CGM devices that do not meet the definition of a therapeutic CGM as defined in CMS Ruling 1682R will be denied as non-covered (no benefit).

[. . .]

There is no Medicare benefit for supplies used with equipment that is not classified as DME.

Local Coverage Policy Article A52464.

Further, the CPT 2013 American Medical Association, Current Procedural Terminology (CPT) Code Book (2013) lists code A9276 as: sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply.

Analysis

The primary issue on appeal is whether Medicare Part B coverage should be provided to the Beneficiary during the dates of service on June 8, 2017 and July 14, 2017. The QIC found that the documentation did not quality for Medicare coverage. The QIC specifically cited Policy Article A52464 that expressly indicated that continuous glucose monitoring is considered precautionary in nature. Based on this information, the QIC found that continuous glucose monitoring was excluded from coverage under the DME benefit because it did not meet the definition of DME under Medicare. Since the item was excluded from coverage under the DME benefit, the Beneficiary was liable for the charges. (Ex. 1 at 5).

The undersigned recognizes the binding authority of CMS Ruling 1682-R, which categorizes the MiniMed as a "non-therapeutic" CGM that is not entitled to coverage. Still, the undersigned reaches a fully favorable decision in this case for two reasons: 1) the sensors (A9276) at issue are necessary for the effective use of a medically reasonable and necessary item that has been found to be DME entitled to Medicare coverage and was provided prior to the Ruling, and 2) the Appellant's use of this MiniMed has been subject to judicial review at the District Court in the Appellant's district, and that court has expressly instructed the Secretary to authorize coverage for this CGM system.

At the hearing, the Beneficiary and his attorney discussed the successful appeals of this same issue before nine different ALJs, and most recently, before the United States District Court in Vermont, the Appellant's home state. The Beneficiary described his hypoglycemic experiences resulting in emergency medical services, and his well-documented necessity for this MiniMed. Attorney Noonan pointed out that nine different peer reviewed publications approve the use of continuous glucose monitors like the MiniMed, and that 98% of private insurers cover the device. In spite of these persuasive arguments, the District Court's instruction to Medicare to pay for the device, and the common-sense recognition that the Beneficiary's MiniMed is a therapeutic device primarily and customarily used to serve a medical purpose, the undersigned is bound in this decision by CMS Ruling 1682-R.

CMS Ruling 1682-R

Background

In response to recent legal actions around the classification and coverage of continuous glucose monitors, CMS issued Rule 1682-R to provide guidance on the issue. Coverage for continuous glucose monitors was originally denied because in the view of the Medicare Appeals Council, CGM are "precautionary" devices that are not "primarily and customarily used to serve a medical purpose", and were therefore excluded from the definition of DME.

Whitcomb v. Hargan, 2:17-cv-14 (E.D. Wis. Oct. 26, 2017), a decision that referred to the "arbitrary and capricious" assertion that CGM were not primarily used to serve a medical purpose, found that the Appeals Council erred when it denied coverage for the plaintiff's

continuous glucose monitor (in that case, a MiniMed). The Court concluded that the phrase "primarily and customarily used to serve a medical purpose" is clear on its face, and that the MiniMed at issue "indisputably satisfies" that requirement. No. 2:17-CV-14 (E.D. Wis. Oct. 26, 2017).

Similarly, the Departmental Appeals Board, Civil Remedies Division, found that Local Coverage Article A52464 (the same article referenced by the QIC in this appeal) failed to meet the reasonableness standard with its statement that "[c]ontinuous glucose monitors are considered precautionary and therefore not covered under the DME [durable medical equipment] benefit." (DAB, C-15-1021, Decision No. CR4596, April 29, 2016).

Most recently, in ***** *v. Azar*, 5:16-cv-121 (Vt. Jan. 30, 2018), the Court opined:

> Here, no evidence supports the [Medicare Appeals Council's] conclusion that a CGM is not "primarily and customarily used to serve a medical purpose." No record evidence suggests that CGMs are used for any nonmedical purpose. The sole evidence upon which the MAC and the Secretary rely is evidence that Dr. ***** continues to monitor his blood glucose levels using a fingerstick, that the CGM system at issue must be calibrated daily using a fingerstick, and that a fingerstick is still required for therapy adjustment. That evidence does not support the MAC's decision.

***** *v. Azar* at 19.

The Court in ***** *v. Azar* further discussed the distinction between CGM that is used in conjunction with traditional finger-stick testing, and CGM that can replace finger-stick testing altogether. The Court held that even when CGM is used with traditional finger-stick testing for confirmation,

> …it performs a function that fingersticks do not… The requirement in 42 C.F.R. § 414.202 that the equipment be "primarily and customarily used to serve a medical purpose" has nothing to do with whether the equipment is the "primary" equipment used to serve that purpose. A beneficiary might need a wheelchair for mobility most of the time, and might also need and use a cane some of the time. The walker or cane is still "primarily and customarily used to serve a medical purpose"…
>
> To the extent that the term "precautionary" is used in NCD 280.1, and in the MBPM to explain why preset portable oxygen units and spare oxygen tanks are not "primarily and customarily used to serve a medical purpose," the evidence in this case does not support the conclusion that [the Beneficiary] uses his CGM as backup or emergency equipment. The evidence is that he uses it routinely to avoid hypoglycemia.

Id. at 20, 21.

Rule 1682-R issued on January 12, 2017, and sought to create a new distinction among CGM: therapeutic and non-therapeutic. Therapeutic CGM is covered DME according to the Rule, and is

defined as CGM that can replace blood glucose monitors for diabetes treatment. If a CGM is approved by the FDA to replace traditional testing, then it qualifies as DME and is entitled to Medicare coverage. On the other hand, CGM that are approved by the FDA "for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions are referred to as 'non-therapeutic' CGMs". Non-therapeutic CGMs do not meet Medicare criteria for covered DME.

At the nucleus of this distinction is the same rationale found in earlier CMS guidance: if a continuous glucose monitor must be used along with traditional blood-glucose testing, then it is precautionary in nature and not "primary" medical equipment; it is secondary or additional equipment. In fact, in its description of therapeutic CGM, the Rule states, "because [therapeutic CGM] are used directly in making diabetes treatment decisions, as opposed to alerting the patient to use a blood glucose monitor to make those decisions, they are not precautionary in nature." The Ruling does not apply to items and services furnished prior to the effective date of the Ruling, January 12, 2017.

The undersigned recognizes that the Appellant's MiniMed is a "non-therapeutic" CGM as contemplated by Rule 1682-R. However, only the sensors of the MiniMed are at issue here. The Appellant's MiniMed system, which was provided to him in 2006, prior to the effective date of the Ruling, has been specifically authorized for coverage in the above cited District Court order. That court is empowered to enter a judgment "affirming, modifying, or reversing the decision [of the Secretary]… with or without remanding the cause for a rehearing." 42 U.S.C. § 405(g); 42 U.S.C. § 1395(ff). The court found that the CGM at issue in that case, the MiniMed currently in use by the Appellant, is covered DME and instructed the Secretary to authorize coverage on the 29th of January, 2018.

The items at issue here are the sensors used by the monitor, which are necessary for the effective use of the Appellant's MiniMed.. Therefore, the undersigned finds that because the MiniMed system was provided before the issuance of Ruling 1682-R, and because this particular MiniMed, litigated in ***** *v. Azar,* has been expressly authorized for coverage, Medicare regulations must also recognize the necessity of payment for items that allow the Beneficiary to use the device. MPBM, Pub. No. 100-02, Ch. 15, Section 110.3. Reimbursement may be made for replacement of essential accessories such as hoses, tubes, mouthpieces, etc., for necessary DME, only if the Beneficiary owns or is purchasing the equipment.

For those reasons, the undersigned finds that the CGM items at issue are covered items that are also medically reasonable and necessary. While acknowledging that the CMS Ruling is the binding authority for rendering this decision, the undersigned finds that in this instance, the sensors must be covered because they are necessary supplies and accessories to be used with DME that was provided prior to the Ruling, and because the particular items that make up this Appellant's MiniMid have been expressly authorized for coverage.

Conclusions of Law

Medicare coverage is approved for A9276 - disposable sensors for a continuous glucose monitoring system, date of service June 8, 2017 and July 14, 2017 because the items are necessary for the effective use of a device that was provided prior to CMS Ruling 1682-R, and has been specifically authorized for coverage under the Medicare DME benefit.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: FEB 22 2018

PMcAfee

P. Arthur McAfee
Administrative Law Judge

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Seattle, Washington

Appeal of:	**J. BLOOM**	OMHA Appeal No.:	**1-7164213198**
Beneficiary:	**J. BLOOM**	Medicare:	**Part B**
HICN:	*******9397A**	Before:	**P. Arthur McAfee** Administrative Law Judge

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Initial, Redetermination and Reconsideration Procedural Documents	1-31
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3	Request for ALJ Hearing	1-24
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5	Post Hearing Documents	1-38

Dated: FEB 22 2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. ***You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.***

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.